MAY 2 8 2002

K013687

NOSE BREATHE® MOUTHPIECE for HEAVY SNORER
2065 S. King Street, Suite 304
Honolulu, HI 96826

3. Premarket Notification

510(K) SUMMARY
OF
SAFETY AND EFFECTIVENESS

4 – 6. See Table of Contents

7. **Description:**

Perlis Device:

A prescription anti-snoring intra-oral mouthpiece with tongue restraint compartment to prevent mouth breathing, the cause of oral dry-out and oral snoring. Molds must be taken to construct the device. The lower molds are used to set the occlusion and not used to construct the device.

Samelson Device:

A prescription anti-snoring mouthpiece of integrally molded acrylic used to displace the tongue in the forward position. It is positioned and secured with the mouth by dental engaging portions located in the incisor area. It has a rearwardly opening socket for cooperation with forward portion of the user's tongue. Molds must be used to construct the device.

Grady Device:

A prescription anti-snoring mouthpiece that is similar in design and purpose as the Samelson device. The major difference being the Grady device has air duct passages on either side of the mouth. It is composed of medical grade silastic having a tongue retractor compartment, in which a vacuum develops at the tip in proportion to the force generated by tongue relapse.

New Device:

A prescription anti-snoring mouthpiece that is similar in design and purpose as the Samelson device. The tongue is placed at the roof of the mouth with a tongue platform holding the tongue in the forward position by a naturally occurring tongue suction and lip seal. It requires upper and lower molds. It is constructed of flexible, thermoforming mouthguard materials.

8. **Summary Describes Intended Use:**

Perlis Device:

It is to mitigate dry mouth problems and oral snoring with the use of a customized mouthpiece. It prevents mouth breathing.

Samelson Device:

It is to control the effects of snoring with a customized mouthpiece. It substantially eliminated oral breathing.

Grady Device:

It reduces the effects of snoring with a universal type oral device, offered in 3 sizes.

New Device:

It reduces snoring by placing the tongue forward to the roof of the mouth. It is customized and requires a prescription.

9. **Technological Characteristics Comparison:**

Similarities:

Although the predicates and the new device have some technological differences, they all employ the same tongue restraint principles and control simple snoring.

All are made by prescription.

All are stabilized in the mouth by registering on a dental arch and employing a forwardly tongue restraint vacuum.

Differences:

The Perlis device registers upon the maxillary dental arch for dentulous, edentulous, those with mixed dentition; and for "daytime use' over an existing maxillary denture; the Samelson device is locked between upper and lower incisor dental engaging portions; the Grady device locks on one portion.

The new device registers upon the maxillary and mandibular arches for dentulous patients.

The Perlis device is concealed; the Samelson and Grady devices protrude beyond the lips.

The new device is within the confines of the oral cavity.

Grady states all oral devices used for snore control have a potential hazard of dislodging and choking the patients. There is always that possibility but the new device has not had a single episode of it happening since its inception in 1997.

The new device has been safely used for over four (4) years.

Efficacy:

All devices perform as intended.

Effectiveness:

The predicates claim effective use of their oral devices, as does the new device in reducing snoring.

Safety:

All four (4) devices can be easily removed with the push of the tongue when expelling anything.

Biocompatibility:

All four (4) devices use medical grade material and have been used by the dental profession for the construction of oral devices.

Summary
Non-Clinical Performance
(Discussion)

10. History and Performance:

After using many different designs and types of dental oral anti-snoring devices, in private practice and from the marketplace, a pre-existing, naturally occurring lip seal and tongue suction were discovered when the tongue is placed at the roof of the mouth. The lip seal and tongue suction are present only during nasal breathing. This discovery lead to the design of a simple, comfortable, non-invasive dental oral anti-snoring device for reducing snoring.

Performance:

Siblings, relatives, and friends have used the new device with excellent results. The new device has performed well and is still being worn by the first-time users for more than four years. The trials have been successful.

11. Clinical Tests:

Clinical tests have not been taken. However, a few hospital sleep lab patients have used the new device after being referred by their physicians. At present, no follow up studies have been made with the new device in place.

12. Non-Clinical Test Conclusions:

The new device has demonstrated to be as safe, effective, and performs as well as the legally marketed oral devices, as necessary to qualify as substantially equivalent. There have been no adverse effects. Siblings, relatives, and friends and their spouses and significant others have all benefited from the reduction in snoring.

The predicates and the new device keep the tongue forward and away from the back of the throat, thereby resulting in the reduction of snoring.

The new device is simple, comfortable, non-invasive, and an effective approach in reducing snoring, in a gentle and safe way.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 8 2002

Dr. Steven K. Sue
C/O Nose Breathe Division
2065 S. King Street, Suite 304
Honolulu, Hawaii 96826

Re: K013687
Trade/Device Name: Nose Breathe Mouthpiece For Heavy Snorer
Regulation Number: None
Regulation Name: Anti-Snoring Device
Regulatory Class: Unclassified
Product Code: LRK
Dated: April 29, 2002
Received: May 3, 2002

Dear Dr. Sue:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013687

510(k) NUMBER (IF KNOWN): K013687

DEVICE NAME: NOSE BREATHE MOUTHPIECE FOR HEAVY SNORER

INDICATIONS FOR USE:

It is a prescription device intended to reduce snoring.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

Susan Runo

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013687